

PTO/SB/08a (01-08)

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Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	1	of	12
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**Complete if Known**

Application Number	10/520,104
Filing Date	January 3, 2005
First Named Inventor	Henry Daniell
Art Unit	1635
Examiner Name	Kubelik
Attorney Docket Number	10669-040

## U. S. PATENT DOCUMENTS

[illegible]

**FOREIGN PATENT DOCUMENTS**

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Examiner Signature	/Anne Kubelik/	Date Considered	09/24/2008
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First Named Inventor	Henry Daniell
Art Unit	1635
Examiner Name	Kubelik
Attorney Docket Number	10669-040

Sheet	2	of	12
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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R1	ABKEVICH, V. et al. "What can disulfide bonds tell us about protein energetics, function and folding: simulations and bioninformatics analysis" Journal of Molecular Biology, 2000, pp. 975-985, Vol 300. No.4.	
	R2	ARAKAWA, T. et al. "Expression of cholera toxin B subunit oligomers in transgenic potato plants" Transgenic Research, 1997, pp. 403-413, Vol. 6, No. 6.	
	R3	BARON, S. et al. "The interferons, Mechanisms of action and clinical applications" JAMA, 1991, pp. 1375-1383, Vol. 266. No. 10.	
	R4	BENDICH, A. J. et al. "Why do chloroplasts and mitochondria contain so many copies of their genome?" BioEssays, June 1987, pp. 279-282, Vol. 6, No. 6.	
	R5	BHOJWANI, S. et al. Plant tissue Culture: Application and Limitations, 1990, Elsevier, Amsterdam, The Netherlands.	
	R6	BOGORAD, L. "Engineering chloroplasts: an alternative site for foreign genes, proteins, reactions and products" Trends Biotechnol., 2000, pp. 257-263, Vol. 18, No. 6.	
	R7	BOVOLENTA, C. et al. "Molecular Interactions Between Interferon Consensus Sequence Binding Protein and Members of the Interferon Regulatory Factor Family, PNAS, 1994, pp. 5046-5050, Vol. 91, No. 11.	
	R8	BRADFORD, M. "A rapid and sensitive method for the quantitation of microgram quantities of protein utilizing the principle of protein-dye binding" Analytical Biochemistry, 1976, pp. 248-254. Vol. 72, No. 1-2.	
	R9	BRAUN, A. et al. "Protein Aggregates Seem to Play a Key Role Among the Parameters Influencing the Antigenicity of Interferon Alphas (IFN-) in Normal and Transgenic Mice" Pharmaceutical Research, 1997, pp. 1472-1478, Vol. 14, No. 10.	

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	R10	BRIXEY, M. et al. "The Chloroplast psbA promoter is more efficient in Escherichia coli than the T7 promoter for hyperepression of a foreign protein" Biotechnology Letters, 1997, pp. 395-400. Vol. 19, No. 4.	
	R11	BRUICK, R. et al. "Light-activated translation of chloroplast mRNAs" Trends in Plant Science, 1999, pp. 190-195, Vol. 4, No. 5.	
	R12	CARLSON, P. S. et al. "The use of protoplasts for genetic research" PNAS, 1973, 598-602, Vol. 70, No. 2.	
	R13	CASTELRUIZ, Y. et al. Hepatology, 1999, pp. 1900-1904.	
	R14	COLAMONICI, O. et al. "Characterization of three monoclonal antibodies that recognize the interferon 2 receptor" PNAS, 1990, pp. 7230-7234, Vol. 87, No. 18.	
	R15	COOK, J. et al. "Differential responsiveness of a splice variant of the human type I interferon receptor to interferons" J. Biol. Chem., 1996, pp. 13448-13453, Vol. 271, No. 23.	
	R16	COWLEY, D. et al. "Expression, purification and characterization of recombinant human proinsulin" FEBS Letters, 1997, pp. 124-130, Vol. 402, No. 2-3.	
	R17	CRAMER, C. et al. "Transgenic plants for therapeutic proteins: linking upstream and downstream strategies" Current Topics Microbiol. Immunol., 1999, pp. 95-118, Vol. 240.	
	R18	CROSS, J. et al. "Constitutive and trophoblast-specific expression of a class of bovine interferon genes" PNAS, 1991, pp. 3817-3821, Vol. 88, No. 9.	

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	R19	CROSSIN, K. et al. "Evidence that microtubule depolymerization early in the cell cycle is sufficient to initiate DNA synthesis" Cell, 1981, pp. 61-71, Vol. 23, No. 1.	
	R20	Daniell, H. et al. "Chloroplast culture. IX. Chlorophyll(ide) a biosynthesis in vitro rates higher than in vivo" Biochem. Biophys. Res. Commun., May 31, 1982, pp. 466-470. Vol. 106, No.2.	
	R21	Daniell, H. et al. "Uptake and expression of bacterial and cyanobacterial genes by isolated cucumber etioplasts" Proc. Natl. Acad. Sci. USA, September 1987, pp. 6349-6353, Vol. 84.	
	R22	Daniell, H. et al. "Transient foreign gene expression in chloroplasts of cultured tobacco cells after biolistic delivery of chloroplast vectors" Proc. Natl. Acad. Sci. USA, January 1990, pp.88-92, Vol. 87, No.1.	
	R23	Daniell, H. et al. "Transient expression of B-glucuronidase in different cellular compartments following biolistic delivery of foreign DNA into wheat leaves and calli" Plant Cell Reports, 1991, pp. 615-619, Vol. 9, No. 11.	
	R24	Daniell, H. et al. "Foreign gene expression in chloroplasts of higher plants mediated by tungsten particle bombardment" Methods Enzymol., 1993, pp. 536-556, Vol. 217.	
	R25	Daniell, H. et al. "Transformation and foreign gene expression in plants by microprojectile bombardment" Methods Mol. Biol., 1997, pp. 463-489, Vol. 62.	
	R26	Daniell, H. et al. "Containment of herbicide resistance through genetic engineering of the chloroplast genome" Nature Biotechnology, April 1998, pp. 345-348, Vol. 16, No. 4.	
	R27	ZHOU, M. et al. "Universal TA cloning" Curr. Issues Mol. Biol., 2000, pp. 1-7, Vol. 2, No. 1.	

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	R28	DANIELL, H. et al. "Medical molecular farming: production of antibodies, biopharmaceuticals and edible vaccines in plants" Trends in Plant Science, May 2001, pp. 219-226, Vol. 6, No. 5.	
	R29	DANIELL, H. et al. "Expression of the Native Cholera Toxin B Subunit Gene and Assembly as Functional Oligomers in Transgenic Tobacco Chloroplasts" Journal of Mol. Biol., 2001 pp. 1001-1009, Vol. 311.	
	R30	DANIELL, H. et al. "Marker free transgenic plants: engineering the chloroplast genome without the use of antibiotic selection" Curr. Genet., 2001, pp. 109-116, Vol. 39.	
	R31	DANIELL, H. et al. "Milestones in chloroplast genetic engineering: an environmentally friendly era in biotechnology" Trends in Plant Science, February 2002, pp. 84-91, Vol. 7, No. 2.	
	R32	DANIELL, H. et al. "Molecular strategies for gene containment in transgenic crops" Nature Biotechnology, 2002, pp. 581-586, Vol. 20.	
	R33	DANON, A. "Translational regulation in the chloroplast" Plant Physiol., 1997, pp. 1293-1298, Vol. 115, No. 4.	
	R34	DE COSA, B. et al. "Overexpression of the Bt cry2 Aa2 operon in chloroplasts leads to formation of insecticidal crystals" Nature Biotechnology, January 2001, pp. 71-74, Vol. 19.	
	R35	DE GRAY, G. et al. "Expression of an Antimicrobial Peptide via the Chloroplast Genome to Control Phytopathogenic Bacteria and Fungi" Plant Physiology, November 2001, pp. 852-862, Vol. 127.	
	R36	DER, S. et al. "Involvement of the double-stranded-RNA-dependent kinase PKR in interferon expression and interferon-mediated antiviral activity" PNAS, 1995, pp. 8841-8845, Vol. 92, No. 19.	

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	R37	DIMMOCK, N. et al. "The immune system and interferon" Introduction to Modern Virology, Fourth Edition, 1994, pp. 205-213.	
	R38	EDWARDS, K. et al. "A simple and rapid method for the preparation of plant genomic DNA for PCR analysis" Nucleic Acids Research, January 2, 1991, pp. 1349, Vol. 19, No. 6.	
	R39	EIBL, C. et al. "In vivo analysis of plastid psbA, rbcL and rp/32 UTR elements by chloroplast transformation: tobacco plastid gene expression is controlled by modulation of transcript levels and translation efficiency", Plant, 1999, pp. 333-345, Vol. 19.	
	R40	EDERBAUM, O. et al. "Expression of active human interferon beta in transgenic plants" J Interferon Res, 1992, pp. 449-453, Vol. 12.	
	R41	FERBAS, J. et al. "CD4+ blood cells are potent producers of IFN-alpha in response to In vitro HIV-1 infection" J Immunol, 1994, pp. 4649-4662, Vol. 152, No. 9.	
	R42	FERNANDEZ-SAN MILLAN, A. et al. "A chloroplast transgenic approach to hyper-express and purify human serum albumin, a protein highly susceptible to proteolytic degradation" Plant Biotechnol J, 2003.	
	R43	GERACE, L. "Cell biology: Traffic control and structural proteins in the eukaryotic nucleus" Nature, 1985, pp. 508-509, Vol. 318, No. 6046.	
	R44	GLICK, B. et al. Molecular Biotechnology: Principles and Applications of Recombinant DNA, 2d edition, 1998, ASM press, Washington, D.C.	
	R45	GOMEX-ORELLANA, et al. "Advances in the oral delivery of proteins" Exp. Opin. Ther. Patents, 1998, pp. 223-234, Vol. 8, no. 3.	

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	R46	GUDA, C., et al. "Stable expression of a biodegradable protein-based polymer in tobacco chloroplasts", Plant Cell Report, 2000, pp. 257-262, Vol. 19.	
	R47	GUTTERMAN, J. et al. "Cytokine therapeutics: lessons from interferon" PNAS, 1994, pp. 1198-1205, Vol. 91, No. 4.	
	R48	RUF, S. et al. "Stable genetic transformation of tomato plastids: high level foreign protein expression in fruits" Nature Biotechnology 2001, pp. 870-875, Vol. 19.	
	R49	HAQ, T. A. et al. "Oral immunization with a recombinant bacterial antigen produced in transgenic plants" Science, May 5, 1995, pp. 714-716, Vol. 268, No. 5211.	
	R50	HAJDUKIEWICZ, P. et al. "The two RNA polymerases encoded by the nuclear and the plastid compartments transcribe distinct groups of genes in tobacco plastids" EMBO J., 1997, pp. 4041-4048, cl. 16, No. 13.	
	R51	HEATH, D. G. et al. "Protection against experimental bubonic and pneumonic plague by a recombinant capsular F1-V antigen fusion protein vaccine" Vaccine, July 1998, pp. 1131-1137, Vol. 16, No. 11-12.	
	R52	HEIFETZ, P. et al. "Protein expression in plastids" Current Opinion in Plant Biology, 2001, pp. 157-161, Vol. 4, No. 2.	
	R53	HENCO, K. et al. "Structural relationship of human interferon alpha genes and pseudogenes." Journal of Molecular Biology, 1985 pp. 227-260, Vol.185, No. 2.	
	R54	ISAACS, A. et al. "Virus interference. I. the interferon" Proceedings of the Royal Society of London. Series B, Biological Sciences, September 1957, pp. 258-267, Vol. 147, No. 927.	

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	R55	KAVANAGH, T. et al. "Homologous plasmid DNA transformation in tobacco is mediated by multiple recombination events" Genetics, 1999, pp. 1111-1122, Vol. 152, No. 3.	
	R56	KIM, J. et al. "Protein disulfide isomerase as a regulator of chloroplast translational activation" Science, December 1997, pp. 1954-1957, Vol. 278.	
	R57	KONG, Q. et al. "Oral immunization with hepatitis B surface antigen expressed in transgenic plants" PNAS, 2001 pp. 11539-11544, Vol. 98, No. 20.	
	R58	KUSNADI, A. et al. "Production of recombinant proteins in transgenic plants: practical considerations" Biotechnology and Bioengineering, 1997, pp. 473-484, Vol. 56, No. 5.	
	R59	LAEMMLI, U. "cleavage of structural proteins during the assembly of the head of bacteriophage T4" Nature, 1970, pp. 680-695, Vol. 227.	
	R60	LAMPSON, G. et al. "Inducers of interferon and host resistance, I. double-stranded RNAs from extracts of penicillium funiculosum" PNAS, 1967, pp. 782-789, Vol. 58, No. 2.	
	R61	LARREA, E. et al. "Journal of Viral Hepatitis, 2001, pp. 1-7, Vol. 8. (cited incorrectly)	
	R62	LENCER, W. I. et al. "Transcytosis of cholera toxin subunits across model human intestinal epithelia" PNAS, October 1995, pp. 10094-10098, Vol. 92.	
	R63	MALIGA, P. "Towards plasmid transformation in flowering plants" TIBTECH, 1993, pp. 101-106, Vol. 11, No. 3.	

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STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	10/520,104
Filing Date	January 3, 2005
First Named Inventor	Henry Daniell
Art Unit	1635
Examiner Name	Kubelik
Attorney Docket Number	10669-040

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	R64	MARTIN, W. et al. "Gene transfer from organelles to the nucleus: how much, what happens, and why?" Plant Physiol., 1998, pp. 9-17, Vol. 118, No. 1.	
	R65	MATHIOWITZ, E. et al. "Biologically erodable microspheres as potential oral drug delivery systems" Nature, March 27, 1997, pp. 410-414, Vol. 386, No. 6623.	
	R66	MAY, G. D. et al. "Application of transgenic plants as production systems for pharmaceuticals" Agricultural materials as renewable resources: nonfood and industrial applications pp. 194-204, Ch. 13, American Chemical Society, Washington, D.C.	
	R67	MCBRIDE, K. E. et al. "Amplification of a chimeric Bacillus gene in chloroplasts leads to extraordinary level of an insecticidal protein in tobacco" Biotechnology, April 1995, pp. 362-365, Vol. 13, No. 4.	
	R68	MORIYA, O. et al. "Induction of hepatitis C virus-specific cytotoxic T lymphocytes in mice by immunization with dendritic cells treated with an anthrax toxin fusion protein" Vaccine, 2002, pp. 789-796, Vol. 20.	
	R69	Muller, U. et al. "Functional role of type I and type II interferons in antiviral defense" Science, 1994, pp. 1918-1921, Vol. 264, No. 5167.	
	R70	NYGREN, P. et al. "Engineering proteins to facilitate bioprocessing" TIBTECH, 1994, pp. 184-186, Vol. 12, No. 5.	
	R71	OHYA, K. et al. "Expressions of two subtypes of human IFN- $\alpha$ in transgenic potato plants" Journal of Interferon & Cytokine Research, Aug. 2001 pp. 585-602, Vol. 21, No. 8.	
	R72	PETRIDES, D. et al. "Computer-Aided process analysis and economic evaluation of for biosynthetic human insulin production" Biotechnology and Bioengineering, 1995, pp. 529-554, Vol. 48, No. 1.	

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	R73	RATHINASABAPATHY, B. "Metabolic engineering of glycine betaine synthesis: plant betaine aldehyde dehydrogenases lacking typical transit peptides are targeted to tobacco chloroplasts where they confer betaine aldehyde resistance" <i>Planta</i> , 1994, pp. 155-162, Vol. 193, No. 2.	
	R74	REICHERT, J. "New biopharmaceuticals in the USA: trends in development and marketing approvals 1995-1999" <i>TIBTECH</i> , 2000, pp. 364-369, Vol. 18, No. 9.	
	R75	RUELLAND, E. et al. "Regulation of chloroplast enzyme activities by thioredoxins: activation or relief from inhibition?" <i>Trends in Plant Science</i> , 1999, pp. 136-141, Vol. 4, No. 4.	
	R76	RUBINSTEIN, M. et al. "The Interferon receptors" <i>CRC Crit Rev Biochem.</i> , 1986, pp. 249-277, Vol. 21.	
	R77	SANFORD, J. C. et al. "Optimizing the biolistic process for different biological applications" <i>Methods in Enzymology</i> , 1993, pp. 483-509, Vol. 217.	
	R78	SIDOROV, V. A. et al. "Stable chloroplast transformation in potato: use of green fluorescent protein as a plastid marker" <i>The Plant Journal</i> , 1999, pp. 209-216, Vol. 19, No. 2.	
	R79	SLOCOMBE, P. et al. "High-level expression of an interferon 2 gene cloned in phage M13mp7 and subsequent purification with a monoclonal antibody" <i>PNAS</i> , 1982, pp. 5455-5459, Vol. 79, No. 18.	
	R80	STAUB, J. M. "Accumulation of D1 polypeptide in tobacco plastid is regulated via the untranslated region of the psbA mRNA", <i>EMBO J.</i> , 1993, pp. 601-606, Vol. 12, No. 2.	
	R81	STAUB, J. M. et al. "High-Yield production of a human therapeutic protein in tobacco chloroplasts" <i>Nature Biotechnology</i> , March 2000, pp. 333-338, Vol. 18, No. 3.	

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	R82	SVAB, Z et al. "high-frequency plastid transformation in tobacco by selection for a chimeric aadA gene" Proc. Natl. Acad. Sci. USA, February 1993, pp. 913-917, Vol. 90.	
	R83	SWAMINATHAN, S. et al. "Affinity purification of recombinant interferon- $\alpha$ on a mimetic ligand adsorbent" Protein Expression and Purification, March 1999, pp. 155-245, Vol. 15, No. 2.	
	R84	THATCHER, D. R. et al. "Related purification of recombinant human IFN- $\alpha$ 2" Methods Enzymol, 1986, pp. 166-177, Vol. 119.	
	R85	TOMPKINS, W. "Immunomodulation and therapeutic effects of the oral use of interferon- $\alpha$ : mechanism of action" Journal of Interferon & Cytokine Research, Aug. 1999, pp. 817-828, Vol. 19, No. 8.	
	R86	TRINCHIERI, G. et al. "Antagonistic effects of interferons on the cytotoxicity mediated by natural killer cell" Federation Proceedings, 1981, pp. 2705-2710, Vol. 40.	
	R87	WALMSLEY, A. M. et al. "Plants for delivery of edible vaccines" Curr. Opin. Biotechnol. April 2000, pp. 126-129, Vol. 11, No. 2.	
	R88	WILSON, V. et al. "A comparison of vertebrate interferon gene families detected by hybridization with human interferon DNA" Journal of Molecular Biology, 1983, pp. 457-475, Vol. 166.	
	R89	YE, G. N. et al. "Optimization of delivery of foreign DNA into higher-plant chloroplasts" Plant Mol. Biol., pp. 809-819, Vol. 15, No. 6.	
	R90	Yu, J. et al. "A plant-based multicomponent vaccine protects mice from enteric diseases" Nature Biotechnology, June 2001, pp. 548-552, Vol. 19.	

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